

Elazaar Rabbani et al.

Serial No.: 09/439,594

Filed: November 12, 1999

Page 9 [Amendment Under 37 C.F.R. §1.115 (In Response To The  
July 30, 2003 Office Action -- August 8, 2003)]

### REMARKS

Claims 146-200 were previously pending in this application. Of those claims, claims 146, 166 and 183 have been amended. Accordingly, as amended above, claims 146-200 are presented for further examination in this application.

#### Claim Amendments

In a sincere effort to define their invention more clearly, Applicants have amended the three independent claims, 146, 166 and 183, as follows. In all three claims, step 1 (A), the phrase "capable of template dependent extension" has been changed to -- which provides for template dependent extension -- . In part (B) of the first step in all three claims, the phrase "being capable of participation" has been changed to -- participate -- . At the end of step 3) in claims 146, 166 and 183, the phrase "and formation of stem-loop structures" has been deleted. Finally, in step 4) (a) in the three claims, the phrase "derived from" has been changed to "formed after."

It is believed that most if not all of the foregoing amendments to claims 146, 166 and 183 have been made in response to the rejection under 35 U.S.C. §112, second paragraph, discussed at pages 4-5 in the July 30, 2003, and also discussed *infra*. Thus, the amendments above are believed to place the pending claims in allowable condition by having adopted the Examiner's suggestions or meeting her objections regarding claim clarity

Entry of the above claim amendments is respectfully requested.

**Withdrawal of Previous Rejections and/or Objections**

Applicants appreciate the indication in the July 30, 2003 that previous rejections and/or objections have been withdrawn, and that the rejections for obviousness-type double patenting and indefiniteness (35 U.S.C. §112, second paragraph) constitute the complete set being applied to this application.

**The Rejection For Obviousness-Type Double Patenting**

Claims 146-200 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 60-68 of copending Application No. 09/104,067. In the Office Action (pages 3-4), the Examiner stated:

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 146-200 are drawn to a process for detecting the presence of a specific target nucleic acid sequence involving using one or more first initial primers which has a first segment (i) being substantially complementary to a portion of said specific target nucleic acid sequence and (ii) capable of template dependent extension and second segment being (i) substantially non-identical to said first segment, (ii) substantially identical to a portion of said specific target nucleic acid sequence (iii) substantially complementary to sequences that are synthesized by extension of the first segment of said first initial primers with said specific target nucleic acid sequence as a template wherein the first initial primers being capable of participation in the formation of a stem-loop structure after said specific target nucleic acid sequences is used as a template for extension. Furthermore, the method involves mixing and incubating the first primer with the reagents for the template dependent extension, forming at least one stem-loop structure and then detecting the presence of the stem-loop structures formed to determine the presence of the specific target nucleic acid. Claims 60-68 of copending Application No. 09/104,067 are drawn a process for linearly amplifying a specific nucleic acid sequence involving the initial

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primer which has the same structure as the first initial primer used in the method of instant claims 146-200. Both the method of instant claims 146-200 and the method of claims 60-68 of copending Application No. 09/104,067 have similar method steps except that the instant invention is for detecting the presence of a specific target nucleic acid and the method of claims 60-68 of copending Application No. 09/104,067 is for amplifying a specific target nucleic acid which is part of the steps in the method of the instant claims 146-200. Thus it would render obvious over the genus method claims 60-68 of the copending Application No. 09/104,067.

While it is noted that the instant application is a divisional of the copending Application No. 09/104,067, the instant claims 146-200 are deemed not patentably distinct from claims 60-64 of the copending Application No. 09/104,067.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

In response, and in a sincere effort to advance prosecution of this application to allowance and issue, Applicants are submitting herewith attached as Exhibit 1 their Terminal Disclaimer To Obviate A Provisional Double Patenting Rejection Over A Pending Second Application. Entry of this paper is respectfully requested.

In view of the timely submission of their Terminal Disclaimer (Exhibit 1), Applicants respectfully request withdrawal of the double patenting rejection.

#### **The Rejection Under 35 U.S.C. §112, Second Paragraph**

Claims 146-200 stand rejected for indefiniteness under 35 U.S.C. §112, second paragraph. In the Office Action (pages 4-5), the Examiner stated:

a. Claims 146-200 are vague and indefinite because of the language "capable of" in claims 146, 166 and 183. It is unclear whether the first initial primer forms a stem-loop structure after said specific target nucleic acid sequence is used as a template for extension. Clarification is required.

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b. Claims 146-200 are vague and indefinite because of the language "derived from" in claims 146, 166 and 183. It is unclear because the segment is synthesized by the extension of the first segment of the first primer from the target nucleic acid used as a template, and the segment is not a derivative with the chemical modification of the extension of the first segment of the first primer from the target nucleic acid used as a template. By in large, the language "derived from" describes a derivative which is chemically modified chemical compound. Thus, it is suggested to clarify uncertainty.

As indicated in the opening remarks of this paper, Applicants have adopted the Examiner's suggestions or have otherwise acceded to her requirements for claim clarity by amending claims 146, 166 and 183 above. In all instances, language with regard to "capable" and "derived" has been deleted from the claims.

In light of the above amendments to the claims, Applicants respectfully request reconsideration and withdrawal of the rejection under §112, second paragraph.

Favorable action on this application is respectfully requested.

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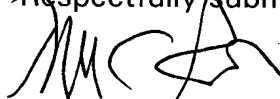
### SUMMARY AND CONCLUSIONS

Claims 146-200 continue to be presented for examination in this application. Claims 146, 166 and 183 have been amended. No other claims have been affected by this paper.

In connection with the Terminal Disclaimer (Exhibit 1) submitted with this Amendment, The Patent and Trademark Office is hereby authorized to charge the requisite small entity fee of \$55.00. No claim fee or any other fee is believed due in connection with the filing of this paper. In the event that any other fee or fees are due, however, The Patent and Trademark Office is hereby authorized to charge the amount of any such fee or fees to Deposit Account No. 05-1135, or to credit any overpayment thereto.

If a telephone conversation would further the prosecution of the present application, Applicants' undersigned attorney request that he be contacted at the number provided below.

Respectfully submitted,



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